Wound Infections Following Implant Removal

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20062

Source
NTR

Brief title
WIFI-2

Health condition

Elective implant removal (IR) after fracture fixation below the level of the knee

Sponsors and support

Primary sponsor: ZonMW
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Proportion of patients with a surgical site infection within 90 days

Secondary outcome

- Other infectious outcomes possibly related to the surgeical procedure

- Cost-effectiveness of intervention
- Target-site antibiotic concentrations
- Tissue oxygenation
- Underlying infections
- Independent predictors of SSI

Study description

Background summary

Rationale: Elective implant removal (IR) after fracture fixation is one of the most common procedures within the orthopaedic/trauma surgery. The rate of surgical site infections (SSIs) in this procedure is quite high, especially below the level of the knee. Antibiotic prophylaxis is not routinely prescribed, even though it has proved to lower SSI rates in other orthopaedic/ trauma surgical procedures.
Objective: The primary objective is to study the effectiveness of a single intravenous dose of 2g of cefazolin on SSIs after IR following fixation of foot, ankle and/or lower leg fractures. Secondary objectives are to study the cost-effectiveness of 2g of cefazolin preventing SSIs after IR, to study target-site antibiotic concentrations and tissue oxygenation, to identify underlying infections, and to identify independent predictors of SSI.
Study design: This is a multicenter, double-blind placebo controlled intervention study
Study population: Adult patients (>17 y/o) undergoing elective implant removal after fixation of a fracture of foot, ankle, lower leg or patella.
Intervention (if applicable): The intervention group receives 2g of cefazolin as preoperative antibiotic prophylaxis, the control group receives a placebo injection.
Main study parameters/endpoints: the main study parameter is the proportion of patients with a SSI.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participating in this trial does not propose additional risk to the patient compared to current practice. Cefazolin has proved to be safe and effective as preoperative antibiotic prophylaxis in this dose. The burden is low for most patients as extra visits to the hospital are not required and questionnaires will take approximately 60 minutes in total. Additional measurements are only applicable to a small proportion of participants at the Amsterdam UMC. For these patients, blood samples will be obtained during surgery, under general or regional anaesthesia and include 3-4 serum samples, 2 target-site blood samples and 2 target-site soft tissue samples. Moreover patients will undergo continuous subcutaneous tissue oxygen tension measurements and measurements of haemoglobin oxygenation in the local microcirculation of the contralateral foot. No extra visits to the outpatient clinic are required when participating in the trial.

Study objective

2gr of Cefazolin is effective as prophylaxis for surgical site infections following implant removal below the level of the knee.

Study design

Start inclusion: January 2020
End of follow up: April 2023 (until 6 months after last IR)
Analysis: May 2023 – July 2023
Implementation: August 2023 – October 2023

Intervention

The intervention group receives 2g of cefazolin as preoperative antibiotic prophylaxis, the control group receives a placebo injection.

Contacts

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Eligibility criteria

Inclusion criteria

- Aged between 18 and 75 years
- Scheduled for IR following fracture surgery of the patella, lower leg, ankle or foot

Exclusion criteria

- Removing and re-implanting osteosynthetic material in the same session
- Active wound infection or (plate) fistula
- A medical history of serious peripheral vascular disease (≥ Fontaine III) Antibiotic treatment at time of IR for a concomitant disease or infection
- A medical history of severe hypersensitivity to penicillin or any other beta-lactam antibiotic

- Severe kidney insufficiency (eGFR < 35)
- Pregnancy and lactation
- Treatment with probenecid, anticoagulants
- Immunosuppressant use in organ transplantation or rheumatoid joint disease
- Insufficient comprehension of the Dutch/English language to understand the patient information to make an informed decision to participate

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-12-2019
Enrollment:	732
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	09-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54651
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8284
CCMO	NL71051.018.19
OMON	NL-OMON54651

Study results

Summary results
N/A